



Bauchtuch

REF 890423

Product Description and Purpose

Unsterilized lap sponges, **4 layers, pre-washed, white**, made of 20 thread dressing gauze, **size 20 cm x 30 cm, with loop and X-Ray chip**. The lap sponge is used for wound care in the OR area, for wound covering, for the absorption of blood and wound fluid and to keep back and hold organs and body tissues. The lap sponges are for single use and they must be sterilized before use with a validated procedure (moist heat in compliance with DIN EN ISO 17665, radiation in compliance with DIN EN ISO 11137, or ethylene oxide in compliance with DIN EN ISO 11135).

Contra-Indications

No contra-indications known, unless there is an allergy attributable to cotton. The X-Ray chip is covered in full by the gauze and is firmly sewn-in. There is no direct contact between the X-Ray chip and the soft tissue or organ tissue.

Composition

Cotton, bariumsulphate, PVC, DINP

Normative and Legal Requirements

The lap sponge (abdominal swab) is a class IIa, rule 7, medical product according to the MDD, the directive 93/42/EEC and the MDR (EU) 2017/745. The lap sponges comply with the requirements of DIN EN ISO 14079.

According to the European standard DIN EN ISO 10993-1 „Biological Evaluation of Medical Devices“, lap sponges are medical products in contact with the body from the outside (vascular system, indirect), and they are classified with the duration of contact A (less than 24 h).

The product does not contain dangerous toxic substances according to REACH. It has CE marking and DIN EN ISO 15223-1 and EN 1041 labels on all its packaging.

Packaging

Primary packaging:	PE bag
Secondary packaging:	carton made of cellulose

Storage

To be stored in a dry and dust-free environment

The product bears the following labels and symbols



Sterilize before use